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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,466	10/14/2003	Nurith Kurn	492692000610	7809

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EXAMINER	
STRZELECKA, TERESA E	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/686,466	KURN, NURITH	
	Examiner	Art Unit	
	Teresa E. Strzelecka	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-30,32,33,35,37-40,45-53,56-60 and 64-67* is/are pending in the application.

4a) Of the above claim(s) *22,23,25,27,29,32,35,37,56-60,64 and 65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-21,24,26,28,30,33,38-40,45-53,66 and 67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/14/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, species A, D, E and H in the reply filed on September 11, 2006 is acknowledged.

2. Claims 22, 23, 25, 27, 29, 32, 35, 37, 56-60, 64 and 65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species and inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 11, 2006.

3. Claims 17-21, 24, 26, 28, 30, 33, 38-40, 45-53, 66 and 67 will be examined.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on October 14, 2003 is partially in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner with respect to references 1-33 presented in the first four pages of the IDS, and with respect to references 1-90 of the second set of four pages of the IDS, as well as references 1 and 2 on the last page of the IDS. References 34-73 listed in the first four pages and references 3 and 4 from the last page of the IDS have not been provided, therefore they were not considered.

Specification

5. The disclosure is objected to because of the following informalities: the first paragraph has not been updated to reflect the current status of the parent application.

Appropriate correction is required.

Sequence Rules Compliance

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

APPLICANT IS GIVEN time of response to this office action WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R. §§ 1.821-1.825. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Specifically, nucleic acid sequences without SEQ ID NOs are present on pages 88, 89, 91-93, 97, 104 and 105. If these sequences were included in the previously submitted sequence listing, Applicant needs to amend the specification to provide SEQ ID NOs for these sequences. If these sequences are not present in the previously submitted sequence listing, Applicant is required to provide a new copy of the CRF and a paper copy of the sequence listing together with a letter stating that the two copies are identical.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 17-21, 24, 26, 28, 33, 38-40, 45, 66 and 67 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 6, 11, 20, 27, 30, 92 and 108 of U.S. Patent No. 6,251,639 (cited in the IDS) in view of Kacian et al. (U.S. Patent No. 5,480,784 A; cited in the IDS).

A) Claim 2 of the '639 patent is drawn to a method for amplifying a target polynucleotide sequence comprising:

(a) hybridizing a single stranded DNA template comprising the target sequence with a composite primer, said composite primer comprising an RNA portion and a 3' DNA portion;

(b) optionally hybridizing a polynucleotide comprising a termination polynucleotide sequence to a region of the template which is 5' with respect to hybridization of the composite primer to the template;

(c) extending the composite primer with DNA polymerase;

(d) cleaving the RNA portion of the annealed composite primer with an enzyme that cleaves RNA from an RNA/DNA hybrid such that another composite primer hybridizes to the template and repeats primer extension by strand displacement to produce displaced primer extension product;

(e) hybridizing a polynucleotide comprising a propromoter and a region which hybridizes to the displaced primer extension product under conditions which allow transcription to occur by RNA polymerase, such that RNA transcripts are produced comprising sequences complementary to the displaced primer extension products,

whereby multiple copies of the target sequence are produced.

Claim 6 is drawn to the method of claim 2, wherein the polynucleotide comprising a termination polynucleotide sequence is a template switch oligonucleotide (TSO), and claim 11 is drawn to the method of claim 2, wherein the polynucleotide comprising a propromoter and region which hybridizes to the displaced primer extension product is a template switch oligonucleotide (TSO).

Claim 20 of the '639 patent is drawn to sequencing a target nucleic acid using rNTPs and rNTP analogs, claims 27 and 92 are drawn to methods of detecting mutation by single strand conformation analysis, claims 30 and 108 are drawn to a method of producing an array.

B) The claims of the 6,251,639 patent do not teach using a second primer hybridizing with an RNA transcript, target polynucleotide being DNA, first and second primers being different, a reverse transcriptase, the RNA-dependent DNA polymerase and RNAse being the same enzyme.

C) Kacian teaches amplification of a DNA template using an autocatalytic reaction using two different primers, one of which hybridizes to an RNA template (Fig. 2a-2e), reverse transcriptase (col. 8, lines 18-27) and the reverse transcriptase with RNAse H activity (col. 8, lines 28-38; col. 17, lines 8-10).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used the RNA template amplification with a second primer of Kacian et al. in the methods of claims of the 6,251,639 patent. The motivation to do so, provided by Kacian et al., would have been that such amplification was autocatalytic and therefore did not require modification of reaction conditions (col. 3, lines 51-56).

9. Claims 17, 30 and 46-53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 6 and 11 of U.S. Patent No. 6,251,639 (cited in the IDS) in view of Kacian et al. (U.S. Patent No. 5,480,784 A; cited in the IDS) and Lockhart et al. (U.S. Patent No. 6,040,138 A).

A) Claim 2 of the '639 patent is drawn to a method for amplifying a target polynucleotide sequence comprising:

(a) hybridizing a single stranded DNA template comprising the target sequence with a composite primer, said composite primer comprising an RNA portion and a 3' DNA portion;

(b) optionally hybridizing a polynucleotide comprising a termination polynucleotide sequence to a region of the template which is 5' with respect to hybridization of the composite primer to the template;

(c) extending the composite primer with DNA polymerase;

(d) cleaving the RNA portion of the annealed composite primer with an enzyme that cleaves RNA from an RNA/DNA hybrid such that another composite primer hybridizes to the template and repeats primer extension by strand displacement to produce displaced primer extension product;

(e) hybridizing a polynucleotide comprising a propromoter and a region which hybridizes to the displaced primer extension product under conditions which allow transcription to occur by RNA polymerase, such that RNA transcripts are produced comprising sequences complementary to the displaced primer extension products,

whereby multiple copies of the target sequence are produced.

Claim 6 is drawn to the method of claim 2, wherein the polynucleotide comprising a termination polynucleotide sequence is a template switch oligonucleotide (TSO), and claim 11 is drawn to the method of claim 2, wherein the polynucleotide comprising a propromoter and region which hybridizes to the displaced primer extension product is a template switch oligonucleotide (TSO).

B) The claims of the 6,251,639 patent do not teach using a second primer hybridizing with an RNA transcript or target polynucleotide being DNA.

C) Kacian teaches amplification of a DNA template using an autocatalytic reaction using two different primers, one of which hybridizes to an RNA template (Fig. 2a-2e).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used the RNA template amplification with a second primer of Kacian et al. in the methods of claims of the 6,251,639 patent. The motivation to do so, provided by Kacian et al., would have been that such amplification was autocatalytic and therefore did not require modification of reaction conditions (col. 3, lines 51-56).

D) Neither the 6,251,639 patent nor Kacian et al. teach labeling the products with rNTPs or microarray hybridization.

E) Lockhart et al. teach analysis of gene expression using microarrays (Abstract).

Regarding claim 30, Lockhart et al. teach labeling of amplified RNA using labeled rNTPs (col. 13, lines 46-49).

Regarding claims 46-48 and 52, Lockhart et al. teach analyzing labeled RNA products using oligonucleotide probe microarray (col. 2, lines 48-67; col. 3, lines 1-6).

Regarding claim 49, Lockhart et al. teach glass substrate (col. 19, lines 51-54).

Regarding claim 50, Lockhart et al. teach immobilization in a two-dimensional configuration (col. 3, lines 7-29).

Regarding claims 51 and 52, Lockhart et al. teach quantitation of transcripts (col. 4, lines 54-56).

Regarding claim 53, Lockhart et al. teach cDNA (col. 8-12).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used the microarray analysis method of Lockhart et al. in the method of claims of the 6,251,639 patent and Kacian et al. The motivation to do so, provided by Lockhart et al., would have been that microarray hybridization detected and quantified expression of about 10,000 genes simultaneously (col. 2, lines 48-55).

10. No claims are allowed. No references were found teaching or suggesting claims 17-21, 24, 26, 28, 30, 33, 38-40, 45-53, 66 and 67, but they are rejected for reasons given above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

Teresa Strzelecka
11/16/06

Notice to Comply	Application No.	Applicant(s)	
	10/686,466	KURN, NURITH	
	Examiner	Art Unit	
	Teresa E. Strzelecka	1637	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Sequences present on pages 88,89,91-93,97,104,105 do not have SEQ ID NOs.

Applicant Must Provide:

☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☐ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
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